K991853

510(k) SUMMARY

PREPARED BY:	INTERNATIONAL DISTRIBUTORS OF ELECTRONICS FOR MEDICINE, INC. (IDEM) 4814 East Second Street Benicia, CA 94510
CONTACT PERSON:	Donna Ward, President
TELEPHONE:	707-746-6334
DATE ON WHICH THE SUMMARY WAS PREPARED:	May 28, 1999
NAME IF DEVICE:	Interacoustics Model EP15 ABR Stand Alone Unit
COMMON NAME:	Evoked Response Auditory Stimulator
PREDICATE DEVICE:	ICS Medical Corp. Chartr EP System

DESCRIPTION OF DEVICE:

The Interacoustics EP15 ABR Stand Alone Unit is a diagnostic tool for computer-based testing. Data is collected in a Windows 95/98 database format that allows for easy inspection of results. The EP15 Stand Alone Unit produces a sound stimulus for use in evoked response measurements or electroencephalogram activation.

Comparison of the Interacoustics Model EP15 and the ICS Medical Chartr EP System:

Indication for use – Identical for both units.

Similarities and differences:

EP15 ABR	Chartr EP
Display Description: 12.1" Wide Angle Industrial TFT	15" SVGA Monitor (others available)
Software Features: Windows 95/98 Operating System	Same
AMPLIFIERS: **Channels:** 2 **Gain:** 80 dB	2 (optionally up to 8) X50 - X5000000
PREAMPLIFIERS: **Frequency response:** 100 to 8000 Hz **CMR Ratio:** >120dB at 50/60 Hz. **Noise:** 5.5nV√Hz, 0.3μV **RMS** (0– 3 kHz); 5.5nV√Hz, 0.5μV **RMS** (100-8000 Hz)	Same >100dB at 50/60 Hz <1.5 μV **RMS** (0.1 Hz – 5 kHz)
Points Per Trace: 450 (30 kHz sample)	600
ANALOG FEATURES: **Low pass:** 1000, 1500, 2000, 3000, 5000 Hz, none (12000Hz). 33 taps FIR filter. **High pass:** None (5 Hz), 50, 100, 150, 300 500 Hz. 6dB/octave.	15 Hz to 25 kHz, 12 dB/octave DC, 0.002 – 1 kHz, 6 dB/octave
STIMULATORS: **Stimuli:** Click, Tone Burst, Blackman, Gaussian, Hanning, Hamming, Bartlett, Rectangle, Manual (rise/plateau/fall) **Parameters for tonal stimuli; frequency, intensity, rise/fall time, plateau duration, envelope shape:** Programmable **Rate:** 7.1, 13.1, 21.1, 23.1, 29.1, 31.1, 35.1, 41.1, 45.1, 49.1 Hz, ext. trigger input **Intensity:** 20 dB to 130 dB peSPL; 10 dB to 100 dB HL In 1 dB step. **Masking:** White noise; masking ear is opposite side of stimulus **Transducers:** EAR 3A Insert Phones-ABR	Click, Tone Burst Programmable 0.1 – 100/sec -12 dB to +128 dB SPL White noise, programmable intensity TDH-49 earphones, insert earphones, bone conduction transducer
SAFETY CHARACTERISTICS: **Optical isolation:** Yes **Built-in isolation transformer:** Yes	Yes Yes

(CONTINUED – COMPARISON)	
EP15 ABR	**Chartr EP**
Controlled parameters: Stimuli Rate; Number of Stimuli; Stimuli Polarity; Click; Tone Burst (frequency, number of sin waves, window); Stimulus Intensity; Number of Curve Pr. Intensity; Intensity (ascend, descend); Soft Attenuator; Stimulus Ear (right, left, simultaneously); Masking Level; Preliminary Filter Setting (low, high pass filter); Recording Onset; Automatic Next Intensity (wave repro level setting); Ext. Trigger Output Duration; Rejection System Rejection Level; Gain (manual, automatic); Display Options (Invert curves on screen; Origin line; Latency Norm. Report Templates; After Filtering; Print out; Manual Stimulus to Familiarization; Talk Forward; Talk Back Monitor.	Stimulated Ear, Masked Ear, Stimulus Intensity, Masking Stimulus, Stimulus Transducer, Stimulus Type, Stimulus Polarity, Stimulus Characteristics, Number of Sweeps Acquires, Stimulus Presentation Rate, Sweep Time, Number of Channels, Amplifier Gain, Filter Characteristics, Inclusion of Notch Filter, Inclusion of Artifact Rejection
Data Collection: Impedance Test; Waveform Buffer (A/B, contra, ipsi-contra, A-B=Noise); Curve (Hide, Fixate, Merge, Delete); Show Online EEG, Store Waveforms in unlimited Storage database	Tests Impedance of Patient Electrode Connections, Display Waveform Buffers During Examination, Displays on-going EEG Activity, Stores Waveforms, Stores the Waveform Presentation
Dimensions: 14" x 10" x 15"	22.5" x 17.5" x 7.8"
Weight: 26.5 lbs.	58 lbs.
Power Supply: Input volts: 90 to 250 VAC Universal Input Switch Mode; Safety: VDE750, EN60601-1, IEC601, IEC1010, UL544, CSA 22.2	200 Watts, 50/60 Hz, 120 or 240 volts
Keyboard: 101-key IBM standard	101 – key IBM standard
Ancillary Functions: Help system. Exports data of one patient to diskette.	Help system. Exports data of one patient to diskette. Backup procedure automatically implemented.

SAFETY AND EFFECTIVENESS:

The Interacoustics Model EP15 ABR Stand Alone Unit is in compliance with the following performance and safety standards:

VDE750; EN 60601-01 (General Safety) Class I, Type BF; EM 60601-1-1 (Safety of Systems); EN 60601-1-2 (EMC); EN 60601-2-26 (Electroencephalographs); EN 60645-3 (Auditory test signals)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 25 1999

Ms. Donna Ward
President
IDEM INTERNATIONAL DISTRIBUTORS OF ELECTRONICS FOR MEDICINE, INC.
4814 East Second Street
Benicia, California 94510

Re: K991853
Trade Name: Interacoustics Model EP15 ABR Stand Alone Unit
Regulatory Class: II
Product Code: GWQ
Dated: August 5, 1999
Received: August 20, 1999

Dear Ms. Ward:

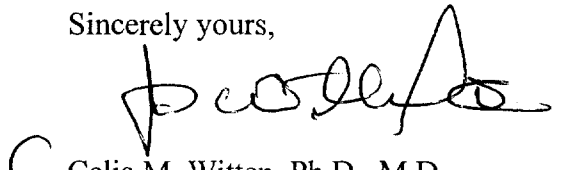
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K991853

Device Name: Interacoustics Model EP15 ABR Stand Alone Unit

Indications For Use:

The Interacoustics EP15 ABR Stand Alone Unit is a diagnostic tool for computer-based testing. Data is collected in a Windows 98 database format that allows for easy inspection of results. The EP15 Stand Alone Unit produces a sound stimulus for use in evoked response measurements or electroencephalogram activation.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K991853

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____